REMARKS

Reconsideration is requested.

Claims 23-25 and 28-59 are pending. Claims 57-59 have been added and find support, for example, in claims 29-31. No new matter has been added. Claims 28, 30, 31 and 49-56 have been withdrawn from consideration as allegedly be drawn to a separately patentable invention. Claims 23-25, 29 and 32-48 are understood to have been examined in so far as they read on the elected sequence (i.e., SEQ ID NO:15).

The Examiner's statement that "A claim drawn to the isolated peptide of SEQ ID NO:15 would be allowable over the prior art." is acknowledged, with appreciation. See, page 11 of the Office Action dated December 30, 2004.

A Rule 181 Petition is being filed separately herewith for the Director to invoke his supervisory authority with regard to the restriction requirement. Consideration and decision on the attached Petition prior to further Action by the Examiner are requested as the most efficient means of prosecution and use of the resources of the Patent Office as well as resources of the applicants.

The applicants Petition for the Director to invoke his supervisory authority and direct the Examiner to withdraw the restriction requirement, at least in so far as the examination of the present application has been reduced the examination to examination of the patentability of a single sequence (i.e., SEQ ID NO:15). The Director is requested to direct the Examiner to examine the claims defined by at least the whole of the Examiner's Group I of the Office Action of September 9, 2004. Examination of the whole of the claimed invention is requested.

The applicants have made an election and requested reconsideration of the restriction requirement. The Examiner has made the restriction requirement final in the Office Action of December 30, 2004.

Consideration of the attached Petition, and a Decision on the same, are requested prior to the issuance of a further Action on the merits by the Examiner as the Decision may change the scope of subject matter to be examined and issuance of a further Action, which could likely be a final rejection closing prosecution, may be contrary to such a Decision.

A statement of the facts involved and point of points to be reviewed and the action requested are contained in the attached Petition, as required by Rule 181. No fee is believed to be required for consideration of the attached Petition as the Petition is only believed to be required due to Patent Office error in the Examiner maintaining the restriction requirement. The Office is authorized however by the attached cover letter to charge the undersigned's Deposit Account No. 14-1140 for any missing or deficient fee required for consideration of the attached Petition.

The Examiner originally required an election of one of eight (8) Groups of subject matter for prosecution in the present application. Moreover, the Examiner required an election of one HCV E1 peptide in the event one of Groups I, III, V and VII were elected, and an election of one HCV E2 sequence in the event one of Groups II, IV, VI and VIII were elected. See, the Office Action dated September 9, 2004.

The applicants elected the subject matter of the Examiner's Group I, relating to HCV E1 peptides, and SEQ ID NO:15, each with traverse.

Reconsideration and withdrawal of the restriction requirement, at least in so far as it requires an election of a single sequence, are requested for any of the following reasons.

The present Examiner also examined the parent application Serial No. 09/566,266, which issued as 6,855,318 on February 15, 2005. The present application claims are similar in structure to the claims of the parent application which issued as the noted patent. The present Examiner did not require an election and/or examination of a single sequence in the parent patent. The present Examiner has not articulated any technical and/or scientific reason why a search of HCV E1 should be any more difficult and/or burdensome than the previous recent search, examination and allowance of claims relating to HCV E2, which recite multiple sequences, in the applicants parent patent.

The following claims, relating to HCV E2, issued from the parent application as the noted patent:

> 1. An isolated HCV E2 envelope peptide as defined by any of SEQ ID NOs: 18-36.
> 2. An isolated HCV E2 envelope peptide consisting of up to 45 contiguous amino acids wherein an amino acid sequence selected from SEQ ID NOs: 18-36 is present in said peptide.
> 3. An isolated peptide selected from the group consisting of:
> a peptide of 21 to 27 contiguous amino acids of SEQ ID NO:20 or 30;
> a peptide of 21 to 29 contiguous amino acids of SEQ ID NO:26;
> a peptide of 21 to 30 contiguous amino acids of SEQ ID NO:22 or 35;
> a peptide of 21 to 31 contiguous amino acids of SEQ ID NO:17 or 34;
> a peptide of 21 to 32 contiguous amino acids of SEQ ID NO:31;
> a peptide of 21 to 33 contiguous amino acids of SEQ ID NO:21;
> a peptide of 21 to 34 contiguous amino acids of SEQ ID NO:18;
> a peptide of 21 to 35 contiguous amino acids of SEQ ID NO:32;
> a peptide of 21 to 37 contiguous amino acids of SEQ ID NO:19;
> a peptide of 21 to 41 contiguous amino acids of SEQ ID NO:33;
> a peptide of 21 to 43 contiguous amino acids of SEQ ID NO:23; and

a peptide of 21 to 44 contiguous amino acids of SEQ ID NO:27.

4. The isolated peptide of any of claims 1, 2 and 3 which is synthesized chemically.

5. The isolated peptide of any of claims 1, 2 and 3 which is synthesized using recombinant DNA techniques.

6. The isolated peptide of claim 5 wherein said peptide is synthesized using a plasmid vector comprising a nucleotide sequence encoding said peptide operably linked to transcription regulatory elements.

7. The isolated peptide of any of claims 1, 2 and 3 which is biotinylated or which is containing cysteine bridges.

8. The isolated peptide of any of claims 1, 2 and 3 which binds and recognizes anti-HCV-related virus antibodies.

9. The isolated peptide of claim 7 which binds and recognizes anti-HCV-related virus antibodies.

10. A combination of peptides comprising a peptide of any of claims 1, 2 and 3.

11. A combination of peptides comprising a peptide of claim 7.

12. A combination of peptides comprising a peptide of claim 8.

13. A composition comprising an isolated peptide of any of claims 1, 2 and 3.

14. A composition comprising an isolated peptide of claim 7.

15. A composition comprising an isolated peptide of claim 8.

16. An assay kit for detecting the presence of anti-HCV-related virus antibodies within a sample of body fluid comprising at least one peptide of any of claims 1, 2 and 3.

17. An assay kit for detecting the presence of anti-HCV-related virus antibodies within a sample of body fluid comprising a combination of peptides of claim 7.

18. An assay kit for detecting the presence of anti-HCV-related virus antibodies within a sample of body fluid comprising a combination of peptides of claim 8.

19. An assay kit for detecting the presence of anti-HCV-related virus antibodies within a sample of body fluid comprising a combination of peptides of claim 10.

20. An assay kit for detecting the presence of anti-HCV-related virus antibodies within a sample of body fluid comprising a combination of peptides of claim 11.

21. A method of immunizing a human against infection with HCV-related virus or any mutated strain thereof, comprising administering to said human at least one peptide according to any one of claims 1, 2 and 3.

22. A method of immunizing a human against infection with HCV-related virus or any mutated strain thereof, comprising administering to said human at least one peptide according to claim 4.

23. A method of immunizing a human against infection with HCV-related virus or any mutated strain thereof, comprising administering to said human at least one peptide according to claim 5.

24. A method of immunizing a human against infection with HCV-related virus or any mutated strain thereof, comprising administering to said human at least one peptide according to claim 6.

25. A method of immunizing a human against infection with HCV-related virus or any mutated strain thereof, comprising administering to said human at least one peptide according to claim 7.

26. A method of immunizing a human against infection with HCV-related virus or any mutated strain thereof, comprising administering to said human a combination of peptides according to any one of claims 1, 2 and 3.

27. A method for diagnosing exposure to or infection by HCV-related viruses comprising:

contacting anti-HCV-related virus antibodies within a sample of body fluid with at least one peptide according to any one of claims 1, 2 and 3, determining the binding of anti-HCV-related virus antibodies within a sample of body fluid with said at least one peptide.

28. The method according to claim 27 wherein said anti-HCV-related virus antibodies are anti-HCV antibodies.

29. A bioassay for identifying a compounds which modulate the interaction between a peptide according to any one of claims 1, 2 and 3 and an anti-HCV-related virus antibody, said bioassay comprising

(i) determining the binding between said peptide and said anti-HCV-related virus antibody;

(ii) contacting said peptide with said compound;

(iii) adding said anti-HCV-related virus antibody to the peptide-compound complex formed in (ii);

(iv) after (iii), determining the binding between said peptide and said compound;

inferring, from (i) and (iv) the modulation of binding between said peptide and said anti-HCV-related virus antibody by said compound.

Claims 23-25 and 28-59 are pending in the present application and are submitted to define a single invention. Examination of all of the pending claims would not be an undue burden on the Examiner as claims of a similar form were examined by the present Examiner in the parent application, presumably without an undue burden.

The applicants note in this regard that all of the pending claims define the common invention relating to E1 peptides and methods of making and using the same,

such as methods of making HCV E1 peptides, methods of using E1 peptides and methods of immunizing humans, diagnostic methods and bioassays of identifying modulators using the same. Moreover, the applicants again submit, with due respect, that the examination of all the claimed subject matter would not place an undue burden on the Examiner.

For completeness, the applicants note that the Examiner's basis for the restriction requirement of a single peptide sequence appears to be an inappropriate extension of the discussion of MPEP § 803.04 (which relates to nucleotide sequences), to peptide sequences.

The applicants further note in this regard that a thorough search must presumably include examination of more than one Class and subclass of subject matter to reasonably assure patentability. The present Examiner, for example, searched the following Classes and Subclasses prior to granting the noted parent patent:

Class 435, Subclasses 5, 7.1, 69.1, and 69.3;

Class 530, Subclasses 317, 321, 324, 300, 325 and 326;

Class 424, Subclasses 185.1, 186.1, 189.1, 204.1 and 228.1;

Class 514, Subclass 2; and

Class 436, Subclass 518.

The above search by the present Examiner in the parent patent includes the subject matter of all of the Examiner's Groups I-VIII of the present application, as well as, many additional Classes and Subclasses.

Absent a complete withdrawal and examination of all the claimed subject matter, withdrawal of the restriction requirement with respect to the subject matter of the

Examiner's Groups I and III, and Groups V and VII is requested as the Examiner has admitted that the subject matter of these combinations of Groups have not been recognized as obtaining a separate status, requiring separate classification, in the Patent Office manual of classification. Accordingly, the Examiner has admitted that a separate search of this subject matter will not be required, demonstrating that a serious burden will not be required of the Examiner. See, MPEP § 803 ("For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02.")

As noted above, the applicants believe the subject matter of all the pending claims should be examined together, consistent with the Examiner's examination in the parent application.

Reconsideration and withdrawal of the restriction requirement are requested.

The Director is also requested in the attached to have the Examiner search the complete breadth of the pending claims and withdraw the requirement for a species election. The applicants again note that the parent application includes allowed claims which read on multiple sequences.

The Examiner has stated in the Office Action of December 30, 2004, that the present Examiner was bound by a prior Examiner's restriction requirement. The Examiner has failed however to support such an assertion by citation to the law, Rules or MPEP. In fact, it has been the undersigned's experience that Patent Office Examiner's regularly do not follow prior Examiner's restriction requirements within a case or between related cases (i.e., continuations and divisional applications), leaving

the applicants at a loss to predict the scope of examination which may be received in related cases. Moreover, the Examiner's comments are contrary to MPEP § 811.02 which states the "restriction is proper at any stage of prosecution up to final action, a second requirement may be made when it becomes proper, even though there was a prior requirement with which applicant complied."

For completeness, the applicants note the Examiner's apparent reliance on *In re Harnisch*, 206 USPQ 300 (CCPA 1980) (copy attached) (see, page 3 of the Office Action dated December 30, 2004) to support the restriction requirement. The Examiner states with regard to the cited case that "the claimed sequences fail as a proper Markush Group" and that the sequences "share no common substantial structural feature." The Examiner concludes that the sequences therefore represent independent inventions.

The MPEP refers to *In re Harnisch* in § 803.02, second paragraph. Interestingly enough, the first paragraph of § 803.02 provides as follows:

> If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.

The Director is requested in the attached to appreciate that claim 23, for example, recites 17 sequences, which the applicants believe to be "few in number" so as to fall within the requirements of the above-quoted paragraph. The Director is also requested in the attached to appreciate the alternative "or" in the above quoted first

sentence such that the MPEP indicates that even if a serious search burden is presented, which it is not in the present case, the existence of sufficiently few members of the claimed group requires examination of the entirety of the claim on the merits (i.e., "the examiner must examine all the members") "even though they are directed to independent and distinct inventions. In such a case, the examiner will ... not require restriction." Id.

As for the Examiner's reliance on *In re Harnisch*, the Court appears to have found that it only be demonstrated that Harnisch's compound claims defined "dyes" to define a "proper" Markush group. See, 206 USPQ 305 ¶[5]. The *Harnisch* Court did not appear to require even a common core structure of the compounds although the court did note that all the claims defined coumarin compounds, even if some of the compounds were intermediates, as alleged by the PTO.

In the present case, the peptides of the claims are HCV E1 peptides, which are submitted to define a single invention, as apparently supported by the *Harnisch* Court.

Withdrawal of the restriction requirement and examination of all of the claimed subject matter are requested.

Absent a complete withdrawal and examination of all the claimed subject matter, rejoinder and allowance of the subject matter of Groups III, VI and VII, as well as any additional pending method claims, once allowable product claims are identified, and an opportunity to amend the method claims as may be required to expedite rejoinder and allowance, as provided for in the Commissioner's Notice published at 1184 OG 86 on March 26, 1996, are requested.

An early and favorable Decision on the attached Petition, prior to the issuance of a further Action by the Examiner, is requested.

The amendments to the specification required by the Examiner at ¶5, on page 4 of the Office Action of December 30, 2004, are believed to have been made in the Preliminary Amendment of October 16, 2003. The Examiner is requested to contact the undersigned in the event anything further is required in this regard. Withdrawal of the objection to the specification stated at ¶5, on page 4 of the Office Action dated December 30, 2004 is requested.

The Section 112, second paragraph, rejection of claims 24, 28, 29 and 32-48 is traversed. Reconsideration and withdrawal of the rejection are requested as the objected-to phrase and claim structure was understood by the Examiner and allowed in the parent issued patent, as quoted above. The claims are definite and withdrawal of the Section 112, second paragraph, rejection is requested.

The Section 112, second paragraph, rejection of claim 29 is traversed. Reconsideration and withdrawal of the rejection are requested as the objected-to phrase and claim structure was understood by the Examiner and allowed in the parent issued patent, as quoted above. The claims are definite and withdrawal of the Section 112, second paragraph, rejection is requested.

The Section 112, first paragraph, rejection of claim 29 is traversed. Reconsideration and withdrawal of the rejection are requested as the specification is enabling for the use of SEQ ID NO:15 in a manner similar to the sequences recited in the parent patent, as quoted above. The claims are supported by an enabling disclosure and withdrawal of the Section 112, first paragraph, rejection is requested.

The Section 102 rejection of claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46 and 47 over Maertens (WO96/04385) is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing remarks.

SEQ ID NO:15 of the present application spans amino acid positions 307-340 of HCV E1, as described, for example, in Table 1 on page 28 of the present application. The sequences identified by the Examiner in the cited Maertens document (i.e., sequences on pages 21-22 and Table 3 of the cited art) are understood to only describe a sequence E1-51 and E1-55 which might include any sequence spanning the region of SEQ ID NO:15. Specifically, E1-51 is understood to span amino acids 301-320 and E1-55 is understood to span amino acids 325-344. At best therefore, E1-51 and E1-55 span 14 amino acids and 16 amino acids, respectively of the region spanned by SEQ ID NO:15 of the present application (assuming the amino acid sequences are the same in this region). These sequences of the cited art therefore do not include SEQ ID NO:15 (see, claim 24) or 21-33 contiguous amino acids of SEQ ID NO:15 (see, claim 25). The cited reference fails to teach each and every aspect of the presently claimed invention. Withdrawal of the Section 102 rejection of claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46 and 47 over Maertens (WO96/04385) is requested.

The Section 102 rejection of claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46 and 47 over Dreesman (WO93/06488) is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing remarks.

SEQ ID NO:15 of the present application spans amino acid positions 307-340 of HCV E1, as described, for example, in Table 1 on page 28 of the present application. The sequence identified by the Examiner in the cited Dreesman document (i.e., SEQ ID

NO:18, Table 3, page 75; Table 4, page 77 and page 132 of the cited document) is understood to only describe a sequence spanning the region of amino acids 291-317. At best therefore, SEQ ID NO:18 of the cited art span 11 amino acids of SEQ ID NO:15 of the present application (assuming the amino acid sequences are the same in this region). SEQ ID NO:18 of the cited art therefore does not include SEQ ID NO:15 (see, claim 24) or 21-33 contiguous amino acids of SEQ ID NO:15 (see, claim 25). The cited reference fails to teach each and every aspect of the presently claimed invention. Withdrawal of the Section 102 rejection of claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46 and 47 over Dreesman (WO93/06488) is requested.

The Section 102 rejection of claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46 and 47 over Wang (U.S. Patent No. 5,747,239) is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing remarks.

SEQ ID NO:15 of the present application spans amino acid positions 307-340 of HCV E1, as described, for example, in Table 1 on page 28 of the present application. The sequence identified by the Examiner in the cited Wang document (i.e., SEQ ID NO:8, Table 8A, columns 43 and 44 of the cited document) is understood to only describe a sequence spanning the region of amino acids 291-330. SEQ ID NO:8 of the cited art is understood to require an "A" at position 330 whereas SEQ ID NO:15 of the present application includes a "T" at position 330. SEQ ID NO:8 of the cited art does not include SEQ ID NO:15 (see, claim 24) or describe a peptide of 21-33 contiguous amino acids of SEQ ID NO:15 (see, claim 25). The peptide of SEQ ID NO:8 of the cited art is 40 amino acids in length. The cited reference fails to teach each and every aspect of the presently claimed invention. Withdrawal of the Section 102 rejection of claims 24,

25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46 and 47 over Wang (U.S. Patent No. 5,747,239) is requested.

The Section 102 rejection of claims 24, 29 and 32-48 over Maertens (U.S. Patent No. 6,245,503) is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing remarks.

SEQ ID NO:15 of the present application spans amino acid positions 307-340 of HCV E1, as described, for example, in Table 1 on page 28 of the present application. The sequence identified by the Examiner in the cited Maertens patent (i.e., SEQ ID NO:67of the cited document) is understood to only describe a 20 amino acid sequence. While there may be a similarity between amino acids 1-17 of SEQ ID NO:67 of the cited art and amino acids 8-23 of SEQ ID NO:15 (amino acid positions 314-329) of the present application, the remaining three amino acids (amino acids 18-20) of SEQ ID NO:67 of the cited art do not correspond to the next contiguous amino acids (i.e., amino acids 24-26 of SEQ ID NO:15, corresponding to acid positions 330-332) of SEQ ID NO:15 of the present application. The 20 amino acid sequence of SEQ ID NO:67 of the cited art does not include SEQ ID NO:15 (see, claim 24). The Examiner's appreciation that claim 25 is novel over the cited patent is acknowledged, with appreciation. The cited reference fails to teach each and every aspect of the presently claimed invention. Withdrawal of the Section 102 rejection of claims 24, 29 and 32-48 over Maertens (U.S. Patent No. 6,245,503) is requested.

The Section 103 rejections of claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46 and 47 over Maertens (WO 96/04385) in view of Choo (PNAS 88:2451-55) or Zonara (Journal of Hepatology 21:858-65), and claims 35, 37, 39, 42, 45 and 48 over

Dreesman, Wang or Maertens in view of Choo and DeLeys (WO 93/18054), are traversed. The secondary references fail to cure the deficiencies of the primary references noted above. The combinations of cited art would not have made it obvious to make the presently claimed peptides or their uses. Withdrawal of the Section 103 rejections are requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested, after a favorable Decision on the attached Petition. The Examiner is requested to contact the undersigned in the event anything further is required in this regard.

Respectfully submitted,

NIXON & VANDERHYE P.C.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

MAERTENS et al. Atty. Ref.: 2551-130; Confirmation No. 5780

Appl. No. 10/685,435 TC/A.U. 1648

Filed: October 16, 2003 Examiner: Lucas

For: MULTI-MER PEPTIDES DERIVED FROM HEPATITIS C VIRUS ENVELOPE PROTEINS FOR DIAGNOSTIC USE AND VACCINATION PURPOSES

* * * * * * * * * * * *

Monday, May 2, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RULE 181 PETITION

The applicants Petition for the Director to invoke his supervisory authority and direct the Examiner to withdraw the restriction requirement, at least in so far as the examination of the present application has been reduced the examination to examination of the patentability of a single sequence (i.e., SEQ ID NO:15). The Director is requested to direct the Examiner to examine the claims defined by at least the whole of the Examiner's Group I of the Office Action of September 9, 2004. Examination of the whole of the claimed invention is requested.

The applicants have made an election and requested reconsideration of the restriction requirement. The Examiner has made the restriction requirement final in the Office Action of December 30, 2004.

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Consideration of the present Petition, and a Decision on the same, are requested prior to the issuance of a further Action on the merits by the Examiner as the Decision may change the scope of subject matter to be examined and issuance of a further Action, which could likely be a final rejection closing prosecution, may be contrary to such a Decision.

A statement of the facts involved and point of points to be reviewed and the action requested are contained herein, as required by Rule 181. No fee is believed to be required for consideration of the present Petition as the Petition is only believed to be required due to Patent Office error in the Examiner maintaining the restriction requirement. The Office is authorized however by the attached cover letter to charge the undersigned's Deposit Account No. 14-1140 for any missing or deficient fee required for consideration of the present Petition.

The Examiner originally required an election of one of eight (8) Groups of subject matter for prosecution in the present application. Moreover, the Examiner required an election of one HCV E1 peptide in the event one of Groups I, III, V and VII were elected, and an election of one HCV E2 sequence in the event one of Groups II, IV, VI and VIII were elected. See, the Office Action dated September 9, 2004.

The applicants elected the subject matter of the Examiner's Group I, relating to HCV E1 peptides, and SEQ ID NO:15, each with traverse.

Reconsideration and withdrawal of the restriction requirement, at least in so far as it requires an election of a single sequence, are requested for any of the following reasons.

Claims 23-25 and 28-59 are pending.

The present Examiner also examined the parent application Serial No. 09/566,266, which issued as 6,855,318 on February 15, 2005. The present application claims are similar in structure to the claims of the parent application which issued as the noted patent. The present Examiner did not require an election and/or examination of a single sequence in the parent patent. The present Examiner has not articulated any technical and/or scientific reason why a search of HCV E1 should be any more difficult and/or burdensome than the previous recent search, examination and allowance of claims relating to HCV E2, which recite multiple sequences, in the applicants parent patent.

The following claims, relating to HCV E2, issued from the parent application as the noted patent:

> 1. An isolated HCV E2 envelope peptide as defined by any of SEQ ID NOs: 18-36.
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> 2. An isolated HCV E2 envelope peptide consisting of up to 45 contiguous amino acids wherein an amino acid sequence selected from SEQ ID NOs: 18-36 is present in said peptide.
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> 3. An isolated peptide selected from the group consisting of:
> a peptide of 21 to 27 contiguous amino acids of SEQ ID NO:20 or 30;
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> a peptide of 21 to 30 contiguous amino acids of SEQ ID NO:22 or 35;
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> a peptide of 21 to 43 contiguous amino acids of SEQ ID NO:23; and
> a peptide of 21 to 44 contiguous amino acids of SEQ ID NO:27.
>
> 4. The isolated peptide of any of claims 1, 2 and 3 which is synthesized chemically.
>
> 5. The isolated peptide of any of claims 1, 2 and 3 which is synthesized using recombinant DNA techniques.

6. The isolated peptide of claim 5 wherein said peptide is synthesized using a plasmid vector comprising a nucleotide sequence encoding said peptide operably linked to transcription regulatory elements.

7. The isolated peptide of any of claims 1, 2 and 3 which is biotinylated or which is containing cysteine bridges.

8. The isolated peptide of any of claims 1, 2 and 3 which binds and recognizes anti-HCV-related virus antibodies.

9. The isolated peptide of claim 7 which binds and recognizes anti-HCV-related virus antibodies.

10. A combination of peptides comprising a peptide of any of claims 1, 2 and 3.

11. A combination of peptides comprising a peptide of claim 7.

12. A combination of peptides comprising a peptide of claim 8.

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14. A composition comprising an isolated peptide of claim 7.

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17. An assay kit for detecting the presence of anti-HCV-related virus antibodies within a sample of body fluid comprising a combination of peptides of claim 7.

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21. A method of immunizing a human against infection with HCV-related virus or any mutated strain thereof, comprising administering to said human at least one peptide according to any one of claims 1, 2 and 3.

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26. A method of immunizing a human against infection with HCV-related virus or any mutated strain thereof, comprising administering to said human a combination of peptides according to any one of claims 1, 2 and 3.

27. A method for diagnosing exposure to or infection by HCV-related viruses comprising:

contacting anti-HCV-related virus antibodies within a sample of body fluid with at least one peptide according to any one of claims 1, 2 and 3, determining the binding of anti-HCV-related virus antibodies within a sample of body fluid with said at least one peptide.

28. The method according to claim 27 wherein said anti-HCV-related virus antibodies are anti-HCV antibodies.

29. A bioassay for identifying a compounds which modulate the interaction between a peptide according to any one of claims 1, 2 and 3 and an anti-HCV-related virus antibody, said bioassay comprising

(i) determining the binding between said peptide and said anti-HCV-related virus antibody;

(ii) contacting said peptide with said compound;

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Claims 23-25 and 28-59 are pending in the present application and are submitted to define a single invention. Examination of all of the pending claims would not be an undue burden on the Examiner as claims of a similar form were examined by the present Examiner in the parent application, presumably without an undue burden.

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that the examination of all the claimed subject matter would not place an undue burden on the Examiner.

For completeness, the applicants note that the Examiner's basis for the restriction requirement of a single peptide sequence appears to be an inappropriate extension of the discussion of MPEP § 803.04 (which relates to nucleotide sequences), to peptide sequences.

The applicants further note in this regard that a thorough search must presumably include examination of more than one Class and subclass of subject matter to reasonably assure patentability. The present Examiner, for example, searched the following Classes and Subclasses prior to granting the noted parent patent:

Class 435, Subclasses 5, 7.1, 69.1, and 69.3;

Class 530, Subclasses 317, 321, 324, 300, 325 and 326;

Class 424, Subclasses 185.1, 186.1, 189.1, 204.1 and 228.1;

Class 514, Subclass 2; and

Class 436, Subclass 518.

The above search by the present Examiner in the parent patent includes the subject matter of all of the Examiner's Groups I-VIII of the present application, as well as, many additional Classes and Subclasses.

Absent a complete withdrawal and examination of all the claimed subject matter, the Director is requested to withdrawal of the restriction requirement with respect to the subject matter of the Examiner's Groups I and III, and Groups V and VII is requested as the Examiner has admitted that the subject matter of these combinations of Groups have not been recognized as obtaining a separate status, requiring separate

classification, in the Patent Office manual of classification. Accordingly, the Examiner has admitted that a separate search of this subject matter will not be required, demonstrating that a serious burden will not be required of the Examiner. See, MPEP § 803 ("For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02.")

As noted above, the applicants believe the subject matter of all the pending claims should be examined together, consistent with the Examiner's examination in the parent application.

Reconsideration and withdrawal of the restriction requirement are requested.

The Director is also requested to have the Examiner search the complete breadth of the pending claims and withdraw the requirement for a species election. The applicants again note that the parent application includes allowed claims which read on multiple sequences.

The Examiner has stated in the Office Action of December 30, 2004, that the present Examiner was bound by a prior Examiner's restriction requirement. The Examiner has failed however to support such an assertion by citation to the law, Rules or MPEP. In fact, it has been the undersigned's experience that Patent Office Examiner's regularly do not follow prior Examiner's restriction requirements within a case or between related cases (i.e., continuations and divisional applications), leaving the applicants at a loss to predict the scope of examination which may be received in related cases. Moreover, the Examiner's comments are contrary to MPEP § 811.02

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which states the "restriction is proper at any stage of prosecution up to final action, a second requirement may be made when it becomes proper, even though there was a prior requirement with which applicant complied."

For completeness, the applicants note the Examiner's apparent reliance on *In re Harnisch*, 206 USPQ 300 (CCPA 1980) (copy attached) (see, page 3 of the Office Action dated December 30, 2004) to support the restriction requirement. The Examiner states with regard to the cited case that "the claimed sequences fail as a proper Markush Group" and that the sequences "share no common substantial structural feature." The Examiner concludes that the sequences therefore represent independent inventions.

The MPEP refers to *In re Harnisch* in § 803.02, second paragraph. Interestingly enough, the first paragraph of § 803.02 provides as follows:

> If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.

The Director will appreciate that claim 23, for example, recites 17 sequences, which the applicants believe to be "few in number" so as to fall within the requirements of the above-quoted paragraph. The Director will appreciate the alternative "or" in the above quoted first sentence such that the MPEP indicates that even if a serious search burden is presented, which it is not in the present case, the existence of sufficiently few members of the claimed group requires examination of the entirety of the claim on the

merits (i.e., "the examiner must examine all the members") "even though they are directed to independent and distinct inventions. In such a case, the examiner will ... not require restriction." Id.

As for the Examiner's reliance on *In re Harnisch*, the Court appears to have found that it only be demonstrated that Harnisch's compound claims defined "dyes" to define a "proper" Markush group. See, 206 USPQ 305 ¶[5]. The *Harnisch* Court did not appear to require even a common core structure of the compounds although the court did note that all the claims defined coumarin compounds, even if some of the compounds were intermediates, as alleged by the PTO.

In the present case, the peptides of the claims are HCV E1 peptides, which are submitted to define a single invention, as apparently supported by the *Harnisch* Court.

Withdrawal of the restriction requirement and examination of all of the claimed subject matter are requested.

Absent a complete withdrawal and examination of all the claimed subject matter, the Director is requested to direct rejoinder and allowance of the subject matter of Groups III, VI and VII, as well as any additional method claims, once allowable product claims are identified, and an opportunity to amend the method claims as may be required to expedite rejoinder and allowance, as provided for in the Commissioner's Notice published at 1184 OG 86 on March 26, 1996.

An early and favorable Decision on the present Petition, prior to the issuance of a further Action by the Examiner, is requested.

Respectfully submitted,

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Court of Customs and Patent Appeals

In re Harnisch

No. 79-614

Decided June 12, 1980

PATENTS

1. Claims — Broad or narrow — Markush type — In general (§20.2051)

Pleading and practice in Patent Office — In general (§54.1)

Patent and Trademark Office has one practice with respect to claims directed to compounds per se, and different one when they are directed to process or composition involving combination of ingredients wherein Markush-type definition-by-enumeration is used in defining process step or composition element.

2. Board of Appeals — Procedure and practice (§19.45)

Claims — Broad or narrow — Markush type — In general (§20.2051)

Patent and Trademark Office Board of Appeals has perfect right to rely on rules, principles, or tenets derivable from cited cases that would enable it to determine whether claims before it were, or were not, in proper form to be examined for patentability, but there is no "doctrine" with respect to Markush practice.

3. Pleading and practice in Patent Office — In general (§54.1)

Patent applications are examined in Patent and Trademark Office for compliance with statutory provisions of 35 U.S.C. 100, 101, 102, 103, and 112; these are considered to be examinations "on the merits."

4. Applications for patent — Divisional (§15.5)

Claims — Broad or narrow — Markush type — In general (§20.2051)

Joinder of invention — In general (§42.1)

Pleading and practice in Patent Office — Rejections (§54.7)

Applicant has right to define what he regards as his invention as he chooses, so long as his definition is distinct and supported by enabling disclosure, but there is possibility of such thing as "improper Markush grouping," although it does not have specific statutory basis.

5. Claims — Broad or narrow — Markush type — Chemical (§20.2053)

Joinder of inventions — Tests of (§42.9)

Claimed compounds that all belong to subgenus that is not repugnant to scientific classification are part of single invention so that there is unity of invention and Markush grouping was proper.

6. Applications for patent — In general (§15.1)

Claims — Broad or narrow — Markush type — In general (§20.2051)

Joinder of invention — In general (§42.1)

Each case involving propriety of Markush groupings must be decided on its facts on case by case basis; Court of Customs and Patent Appeals adheres to holding in In re Weber, 198 USPQ 328, and In re Haas, 198 USPQ 334; unity of invention concept is not to be confused with "misjoinder" under 35 U.S.C. 121 rejection; "unity of invention" is appropriate term to apply where unrelated inventions are involved, that is, inventions that are truly independent and distinct.

7. Court of Customs and Patent Appeals — Issues determined — In general (§28.201)

Alleged error that is not argued is deemed abandoned.

Particular patents — Dyestuffs

Harnisch, Coumarin Compounds, rejection of claims 1 and 3 through 8, reversed.

Appeal from Patent and Trademark Office Board of Appeals.

Application for patent of Horst Harnisch, Serial No. 559,978, filed Mar. 19, 1975. From decision rejecting claims 1 and 3 through 8, applicant appeals. Reversed.

Leonard Horn, New York, N.Y., for appellant.

Joseph F. Nakamura (Fred E. McKelvey, of counsel) for Commissioner of Patents and Trademarks.

Before Markey, Chief Judge, Rich, Baldwin, and Miller, Associate Judges, and Ford, Judge.*

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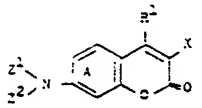
* The Honorable Morgan Ford, Judge, United States Customs Court, sitting by designation.

This appeal is from the decision of the United States Patent and Trademark Office (PTO) Board of Appeals (board) rejecting, under 37 CFR 1.196(b), claims 1 and 3-8[1] of appellant's application, serial No. 559,978, filed March 19, 1975, for "Coumarin Compounds," on the sole ground that these claims are "drawn to improper Markush groups." We reverse.

The Invention

The claimed compounds encompass coumarin compounds useful as dyestuffs. Some of them may be used as intermediates to make other dyestuffs. Claim 1 is representative and reads as follows:

1. Courmarin compounds which in one of their mesometric limiting structures correspond to the general formula



wherein

X represents aldehyde. azomethine. or hydrazone.

R' represents or alkyl.

Z' represents hydrogen. alkyl. cycloalkyl. araikyl. aryl or a 2- or 3-membered alkylene radical connected to the 6-position of the coumarin ring and

Z² represents hydrogen. alkyl. cycloalkyl. or a 2- or 3-membered alkylene radical connected to the 8-position of the coumarin ring

and wherein

Z' and Z² conjointly with the N atom by which they are bonded can represent the remaining members of an optionally benz-fused heterocyclic ring which. like the ring A and the alkyl. aralkyl. cycloalkyl and aryl radicals mentioned. can carry further radicals customary in dye-stuff chemistry.

Claims 3-6 depend from claim 1, adding further limitations with respect to the substitutents; claim 7 is an independent claim of the same type as claim 1 but of much greater length in naming substituents. and claim 8 depends therefrom as well as from claim 4.

The instant coumarins are said to be useful for dyeing synthetic or natural fibers, plastics, and liquids such as oils and lacquers. Of apparently significant commerical value is the dyeing of either the aqueous or organic based inks preferred in rotary gravure printers for non-textile articles.

Clear shades of yellows to oranges are purportedly achieved with good fastness properties. In addition. a strong chartreuse to yellow fluorescence supposedly occurs upon exposure to either natural or ultraviolet light. The fluorescence is said to be especially suitable for tunable dye lasers.

The Rejection

The examiner. relying on no prior art. rejected claims 1 and 3-8 under 35 USC 121 "as containing an improper Markush group and misjoinder." More explicit reasons were said to be set forth in the earlier Office Action of May 12. 1976. In that action the examiner enumerated ten species of compounds encompassed by the claims. Beside each group he listed the various PTO class 260 subclasses into which the species fall.

The significance of this segmentation was declared to be twofold. In the examiner's words.

> A reference anticipating one member [of the listed groups] would not render any other member obvious under 35 USC 103. The members are not so few in number or so closely related that a search and examination of the entire claim cannot be made with [sic. without?] serious burden.

The Board

The board summarily reversed the rejection of the appealed claims under 35 USC 121. Citing our decisions in In re Weber. 580 F.2d 455. 198 USPQ 328 (CCPA 1978). and In re Haas. 580 F.2d 461. 198 USPQ 334 (CCPA 1978), decided subsequent to the examiner's rejection. the board stated that "35 USC 121 does not form the basis for rejection of a claim * * *."

A new rejection was then made by the board under 37 CFR 1.196(b),[2] rejecting the claims as "drawn to improper Markush groups." After a lengthy listing of decisions from 1925 to 1953 reviewing "Markush practice," by the Commissioner. the board.

[1] The board also newly rejected claim 6 as indefinite under 35 USC 112 due to an improper dependence and claim 8 as improperly dependent from two claims. 7 and 4. Appellant acknowledges in his brief that no appeal is taken from either of these rejections. wherefore we need not consider them.

[2] 37 CFR 1.196(b), in relevant part. reads:

(b) Should the Board of Appeals have knowledge of any grounds not involved in the appeal for rejecting any appealed claim. it may include in its decision a statement to that effect with its reasons for so holding. which statement shall constitute a rejection of the claims. * * *

and this court,[1] the board expounded its theory of the propriety of its new "improper Markush group" rejection solely on the basis of "judicially created doctrine," as follows (our emphasis):

> Applying the facts of this case to the principles enunciated, we find that the members of the Markush groups of the claims do not belong to a known or recognized genus and possess widely different physical or chemical properties. Aside from the obvious fact that the compounds encompassed by the claims are *not functionally equivalent*, said compounds, considered as a whole, *are so dissimilar and unrelated chemically or physically that it would be repugnant to accepted principles of scientific classification to associate them together in a generic group*. For example, the types of derivatives encompassed by the Markush claim may include polyfused N-heterocyclics, cyclic, acyclic and aromatic amines, aryloxyalkylamines, amides, sulfonamides, phthalimides, quaternary ammonium salts, phosphorous heterocyclics, phosphates, aldehydes, azomethines, hydrazones, ethers, esters, halogens, alcohols, nitriles, piperidines, furanes, pyrroles, indoles, amongst others. It is clear that on this record the involved compounds *cannot be considered functionally equivalent*, in fact, some being no more than intermediates for the others. The foregoing is borne out by the record wherein appellant discloses that *the various groups of compounds possess different physical or chemical properties*. Nowhere in the record has it been established or even alleged that the variety of compounds included within the explicit scope of the claims are recognized by the art as being functionally equivalent. The functional groups involved herein, as emplified above, are so structurally diverse they would be expected to possess dissimilar and unrelated chemical and physical properties. *The mere fact that there is a single structural similarity (i.e., the coumarin group) is not in itself sufficient reason to render all the embodiments functionally equivalent, particularly when the ultimate properties of the final products could not be expected to possess any recognized functional relationship*. Thus, the fact that the coumarins are in most part indicated as being dyestuffs (others being intermediates for dyes) is not sufficient, since, depending upon their structure, they may be subject to different modes of application and use.

Appellant's Position

Appellant, picking up the board's statement that its rejection "has basis in judicially created doctrine," as shown by the cases it cited, rather than in the patent statutes, asks this court, first: whether claims can be rejected on a judically-created doctrine rather than on some statutory basis, such as 35 USC 121 on which the examiner relied. If they can, then appellant asks, second, whether the compounds claimed are sufficiently closely related to be joined in the same claim.

On the first point, appellant seems to assume some unstated specific "doctrine" on which the board acted, against which he inveighs, and which he says cannot stand, urging us not to create a "doctrine."

On the second point, appellant discusses the fact situation underlying the appealed claims, showing that the compounds are all dyestuffs, that the members of group X, claim 1, are closely related, that the compounds are all coumarins, and cites two board opinions reversing rejections by the examiner of claims structured similarly to

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[1] As detailed by the board:

> Markush practice has a long history in the Office dating back to at least Ex parte Markush, 1925 CD 126, 340 OG 839. Since that time, the Office and the Court of Customs and Patent Appeals had considered rejections based on the propriety and/or limitations of Markush-type claims. See, for example, Ex parte Palmer et al., 1930 CD 3, 398 OG 707; Ex parte Burke, 1934 CD 5, 441 OG 509; Ex parte Dahlen, 1934 CD 9, 441 OG 510; In re Swenson et al., 30 CCPA 764, 132 F.2d 336, 1943 CD 175, 56 USPQ 180 (1942); In re Haas et al., 31 CCPA 895, 141 F.2d 122, 1944 CD 234, 60 USPQ 544 (1944); In re Kingston, 32 CCPA 1013, 149 F.2d 181, 1945 CD 297, 65 USPQ 371 (1945); In re Ruzicka et al., 32 CCPA 1163, 150 F.2d 550, 1945 CD 449, 66 USPQ 226 (1945); In re Archbold, 33 CCPA 725, 151 F.2d 350, 1946 CD 63, 67 USPQ 102 (1945); In re Thompson et al., 33 CCPA 942, 154 F.2d 189, 1946 CD 280, 69 USPQ 148 (1946); In re Winnek, 34 CCPA 946, 160 F.2d 572, 1947 CD 280, 73 USPQ 225 (1947); In re Jones, 34 CCPA 1150, 162 F.2d 479, 1947 CD 484, 74 USPQ 149 (1947); In re May et al., 36 CCPA 833, 172 F.2d 593, 1949 CD 119, 80 USPQ 515 (1949); In re Schechter et al., 40 CCPA 1009, 205 F.2d 185, 1953 CD 323, 98 USPQ 144 (1953).
>
> Additional analysis of Markush practice appears particularly in the following articles:
>
> Kelly et al., Markush Claims, 37 JPOS 164 (1955), (a 75-page exhaustive review of the practice by a committee of the Michigan Patent Law Association).
>
> Walterscheid, Markush Practice Revisited, 61 JPOS 270 (1979).

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appellant's claims. namely. Ex parte Brouard. 201 USPQ 538 (Bd. App. 1976). and Ex parte Taylor. 167 USPQ 637 (Bd. App. 1969). The former case. like this one. involved a claim 24 to a dyestuff defined by structure containing. inter alia. a substituent "B" the definition of which included a list of alternatives occupying about a column in the USPQ report. The rejection reversed was on the ground of "improper Markush group" and misjoinder of independent and distinct inventions.

The PTO Position

The solicitor's brief contains helpful digests of certain key cases selected from the many which discuss "Markush practice" from its inception in 1924 through 1979. It supports the board's new rejection on the ground the claims are drawn to "improper Markush groups." After stating that "Markush practice" is one of long standing and involves a vast body of precedent. the brief relies primarily on the following contentions: (1) there need not be a specific statutory basis for the rejection. citing by analogy obviousness-type double patenting rejections which are case-law based; (2) the materials set forth in the "Markush group" ordinarily must belong to a recognized physical or chemical class or to an art-recognized class; and (3) the claimed group must not be "repugnant to accepted principles of scientific classification."

A principal factual contention in the solicitor's brief is that appellant's claimed compounds include (1) dyestuffs. (2) intermediates for making dyestuffs. or 3) both. and fails to reveal the utility per se of each compound. However. at oral argument the solicitor announced with admirable candor that. having considered appellant's reply brief. he had concluded that there is in fact no class "(2)" because all of the claimed compounds are dyestuffs though some of them could also be used as intermediates to make still other dyestuffs.

The solicitor also cited authority to the effect that each "improper Markush" case must be decided on the basis of its own facts. He also stated that current PTO "Markush practice" is as set forth in section 706.03(v) of the Manual of Patent Examining Procedure (MPEP). 3d ed., Rev. 46. July 1976. reproduced in full as an appendix hereto.

Opinion

We will first express our views concerning the PTO's reliance on "judicially created doctrine" in its rejection of claims for "improper Markush grouping." Appellant injected this point into the case by contending that the PTO had no right to rely on doctrine because a statutory basis for rejection must be stated. He also seems to contend that there is no "doctrine" and that while this court could create one it should not do so. In consequence. much of the oral argument was involved with the court trying to find out from the solicitor what. if any. "doctrine" was being relied on by the PTO. no clear answer being forthcoming — with good reason.

Upon reflection and consideration of the cases cited by the board. the discussion of those and others by the solicitor. and the recorded history of Markush practice. it appears to us that all of the discussion of "doctrine" is beside the point because there is no "Markush doctrine." Appellant never made clear or specific what "doctrine" he was referring to and the solicitor. justifiably. was unable to point one out to us.

"Markush" was the name of an applicant for patent (Eugene A. Markush) who happened to use in a claim a type of definition of a genus or subgenus by enumeration of species. which he did not devise and which had been used before in patent claims.[3] The examiner considered the claim to be "alternative" in form. objected to it. and Markush petitioned the Commissioner. Assistant Commissioner Kinnan. in Ex parte Markush. 1925 CD 126 (Com. Pat. 1924). approved the form of claim and granted the petition. thus requiring the examiner to examine it for patentability. Thus the name "Markush" became attached to a type of claim expression. and that is all it connotes. As others rang changes on the type of expression used by Markush and approved by Assistant Commissioner Kinnan. further decisions and opinions on petitions and in appeals ensued and a considerable body of case law evolved. approving and disapproving various forms of Markush-type expression. from which cases a number of *rules* can be deduced. Like other bodies of case law. however. the body pertaining to what may properly be called Markush *practice* has not been altogether consistent and has evolved through the years. Among the

[3] The Markush opinion points out that in another division of the Patent Office claims "of this character" have been allowed. citing Patents Nos. 1,472,048 and 1,486,635. and that. long before that. Patent No. 901,675 contained claims in which "the letter R is used in a chemical formula as standing for CH_3 or COOH" and that such claims had frequently been allowed. Markush ultimately obtained Patent No. 1,506,316. Aug. 26. 1924.

inconsistent decisions, some of them were by this court. In the PTO, one of the changes that took place was the abandonment of the rule against the use of "or" in an enumeration of alternative materials that might be used in a claimed invention, which rule was the basis of the objection giving rise to the Markush decision. A specific example will be found in MPEP 706.03(v). Not long ago, by a Notice under date of May 1, 1974, the PTO set up a "Practice Re Markush-Type Claims" and later incorporated the Notice in MPEP section 803. Since the MPEP revision of July 1978, that practice has not been followed because of two decisions of this court and MPEP 803 now contains this statement:

Practice Re Markush-Type Claims

The subject matter formerly under this subtitle has been cancelled in view of the decisions In re Weber et al., 198 USPQ 328 (CCPA 1978), and In re Haas, 198 USPQ 334 (CCPA 1978).

Thus have decisions changed the Markush practice.

[1] It is also clear that Markush practice does not refer to a *single* rule. As may be seen from MPEP 706.03(v), set forth in the appendix, the PTO has one practice with respect to claims directed to compounds per se and a different one when they are directed to a process or composition involving a combination of steps or ingredients wherein the Markush-type definition-by-enumeration is used in defining a process step or composition element.

In summary, there is no "doctrine" to be considered but only a body of case law, emanating from both "higher" and "lower" authority, not altogether consistent, the latest decisions tending to carry the most weight as precedent.

[2] Coming now to appellant's first contention that the board had no right to rely on "judically created doctrine," we note that a doctrine, by definition, is, according to Black's Law Dictionary, revised 4th ed., "A rule, principle, theory, or tenet of the law." As is clear from the entire board opinion, what it meant was that it intended to rely on rules, principles, or tenets derivable from the cases it cited which would enable it to determine whether the claims before it were or were not in proper form to be examined for patentability. Our ruling on this point is that it had a perfect right to do so. But there is not one "doctrine" or rule; there are many.

The next questions are whether the board correctly interpreted the facts and whether it correctly applied the rules of law derivable from the cases to the facts. Before considering these questions, we take note of some recent history respecting Markush practice.

[3] In the PTO, patent applications are examined for compliance with the statutory provisions of Title 35, United States Code, as set forth in sections 100, 101, 102, 103, and 112. These are considered to be examinations "on the merits." There are also procedural questions arising under section 121 and related PTO rules concerned with "restriction practice." See MPEP, Chapter 800. As shown by the In re Haas cases, issues arose from PTO refusal to consider on the merits single claims to groups of chemical compounds of broad scope unless each claim was first broken up into a plurality of claims of lesser scope. The first PTO position was that it would neither consider *nor reject* the claims, thus foreclosing appeal to the board or to this court. After this position was held to be a rejection, the PTO promulgated its May 1, 1974 Notice, which authorized rejection on the basis of §121, relating to restriction, thus combining the two matters of Markush practice and restriction practice. In Haas II (see note 6, supra), this court held that §121 could not be used as the basis for rejecting a *single* claim or compelling its replacement by a plurality of narrower claims before examination on the merits would be made. Haas II was decided at the same time as In re Weber, supra, involving similar issues, and Haas II was decided on the basis of the opinion in Weber. We note that in Weber the majority opinion regarded the "improper Markush grouping" reasoning of the board as having been merely "supportive of the rejection under §121 rather than alternative to it" and dealt only with the §121 rejection, reversing it and remanding the case to the PTO for consideration, separately, of the "improper Markush" rejection. The concurring opinion, by the present writer, pointed out with respect to that remand, that there existed a vast body of case law relating to Markush practice. We have not yet heard again from Weber, but the present case comes to us in similar posture. Note that this case involves an improper Markush rejection by the examiner based on §121 which the board reversed in view of

Ex parte Haas, 175 USPQ 217 (Bd. App. 1972), reversed, In re Haas, 486 F.2d 1053, 179 USPQ 623 (CCPA 1973)("Haas I"). Ex parte Haas, 188 USPQ 374 (Bd. App. 1975), reversed, In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978)("Haas II").

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80 F.2d 461, 198 USPQ 334 (CCPA
II").

Weber, substituting its own improper Markush rejection based only on judicial precedent and divorced from §121.

[4] Anent appellant's argument that the board should not be allowed to rely solely on judicial precedent, we think it should be clear from our actions in Weber and Haas II that we there recognized the *possibility* of such a thing as an "improper Markush grouping." We were and are aware that it does not have a specific statutory basis, as we are aware of an applicant's right to define what he regards as his invention as he chooses, so long as his definition is distinct, as required by the second paragraph of §112, and supported by enabling disclosure, as required by the first paragraph of §112. In re Wakefield, 57 CCPA 959, 422 F.2d 897, 164 USPQ 636 (1970); In re Borkowski, 57 CCPA 946, 422 F.2d 904, 164 USPQ 642 (1970).

In the early years of the development of Markush practice, many of the cases involved the problem of clarity — avoiding the uncertainties of alternatives and the like. More recently, the cases have centered on problems of scope, which are related to enablement. Assuming enablement, however, there remains a body of Markush-practice law regarding Markush-type claims, particularly in the chemical field, concerned more with the concept of what might be better described as the concept of unity of invention. At least the term would be more descriptive and more intelligible internationally than is the more esoteric and provincial expression "Markush practice." It is with this unity of invention concept in mind that we approach the propriety of the appealed claims.

Over thirty years ago this court decided In re Jones, 34 CCPA 1150, 162 F.2d 479, 74 USPQ 149 (1947), reversing an "improper Markush group" rejection of claims to chemical compounds which were growth-regulating compositions for plants, fungicides, and insecticides. Notwithstanding their various properties, the court found all of the compounds included in the claims were plant growth stimulants, thus having a common function. The court noted that in any Markush group the compounds "will differ from each other in certain respects." It laid down the proposition, with which the PTO agrees in its MPEP, that in determining the propriety of a Markush grouping the compounds must be considered as wholes and not broken down into elements or other components. It also held, in agreement with the board, that each case of this type must be considered on its own facts. Citing Ex parte Clark, 11 USPQ 52 (Com. Pat. 1931), a case decided by the author of the original Markush opinion, it noted that "the inclusion in Markush groups of compounds which differed widely in some respects," namely, aliphatic, aromatic, and aralkyl compounds, had been permitted. It cited Ex parte Dahlen, 42 USPQ 208 (Bd. App. 1938) as permitting the grouping of compounds having the same nuclei but side chains wherein there was a wide variation. It found the claims before it to cover compounds all belonging to a genus of tetralyl compounds having a substituted methyl group at position 6 and ruled that they had a community of properties justifying their grouping which was not repugnant to principles of scientific classification.

[5] We regard the present case as similar to In re Jones, supra, and also the much later decision of the board in Ex parte Brouard, supra, in which the board reversed the examiner's "improper Markush" rejection. We conclude that the board here was factually in error in not recognizing that all of appellant's claimed compounds are dyes, as confirmed by the solicitor's admission. The board's reliance on its notion that some of the claimed compounds are "no more than intermediates" overlooked the now admitted fact that they are dyes as well. Clearly, they are all coumarin compounds which the board admitted to be "a single structural similarity." We hold, therefore, that the claimed compounds all belong to a subgenus, as defined by appellant, which is not repugnant to scientific classification. Under these circumstances we consider the claimed compounds to be part of a single invention so that there is unity of invention as was held to be the case in Ex parte Brouard, supra, 201 USPQ at 540. The Markush groupings of claims 1 and 3-8 are therefore proper.

[6] As stated above, we decide this and like cases on their facts on a case-by-case basis. It should also be clear from what we have said that we adhere to our holdings in In re Weber, supra, and In re Haas (Haas II), supra. Nothing we have said herein is intended to change or modify them in any way; nor do we think anything said could be reasonably construed to have such an effect. The "unity of invention" concept is not to be confused with the "misjoinder under 35 USC 121" rejection employed in In re Weber. In Weber we dealt with the use of 35 USC 121, which deals only with restriction requirements, to support the rejection of a single claim. Here we are concerned only with the rejection of a single claim on the distinct ground that it is directed to an "improper Markush group." Reference to the

widely-recognized concept of "unity of invention" has been made in order to suggest an appropriate term to apply where *unrelated* inventions are involved — inventions which are truly independent *and* distinct.[*] This case, we find, does not involve such inventions.

[7] Appellant expressly stated in his brief that no appeal was being taken from the rejection of claim 6 under 35 USC 112 or of claim 8 as improperly dependent. In addition, while appellant's reasons of appeal alleged error in the board's supposed dismissal of claims 9-14 and 23-25, this alleged error has not been argued and is therefore deemed abandoned. The appeal with respect to claims 6, 8-14, and 23-25 is therefore *dismissed*.

The board's rejection of claims 1 and 3-8 as based on "improper Markush groups" is *reversed*.

Reversed

[Appendix omitted.]

Court of Customs and Patent Appeals

Southwire Company v. U.S. International Trade Commission et al.

No. 80-21

Decided June 2, 1980

UNFAIR COMPETITION

1. Court of Customs and Patent Appeals — Jurisdiction (§28.25)

Court of Customs and Patent Appeals, under Section 337(c) of Tariff Act of 1930, has jurisdiction to review International Trade Commission determination in same manner and subject to same limitations and conditions as decision of Customs Court; original appeal from decision of Customs Court must be filed within sixty days after final judgment or order; however, cross-appeal from decision of Customs Court may be filed within fourteen days of date on which first original appeal is filed, even if sixty day appeal period has expired.

2. Court of Customs and Patent Appeals — In general (§28.01)

Court of Customs and Patent Appeals — Jurisdiction (§28.25)

Section 337(c) of Tariff Act of 1930 directs Court of Customs and Patent Appeals to treat International Trade Commission like Customs Court in matters of appellate procedure; subsection (c) language was merely shorthand substitute for express procedural provisions parroting those that control procedure in customs appeals; however, effect of section is same, i.e., procedural rules applicable in customs appeals are carried over into ITC practice; thus, Section 337 creates exception to Fed.R.App.P. 20 by making available in ITC practice same fourteen day cross-appeal period available in customs practice.

3. Court of Customs and Patent Appeals — Jurisdiction (§28.25)

Dismissals of first appeals that foreclosed need to file cross-appeals negates any effect of those appeals on cross-appeal period; establishment of separate period for cross-appeals serves salutary purpose of avoiding needless employment of judicial process involved in filing of original appeals in cases in which no such original appeals would be filed in absence of appeal by adversary.

4. Court of Customs and Patent Appeals — Jurisdiction (§28.25)

Rule respecting cross-appeals does not merely enlarge period for original appeal from sixty days to seventy-four days from date of decision being appealed; on contrary, cross-appeal period is fourteen days from first original appeal, without regard to decision date; under Section 337(g) of Tariff Act of 1930, International Trade Commission's positive Nov. 23, 1979 determinations did not become appealable until Jan. 23, 1980; however, Court of Customs and Patent Appeals expresses no view respecting appeal period applicable to original appeals from negative portions of ITC determinations containing both positive and negative findings.

5. Court of Customs and Patent Appeals — Issues determined — In general (§28.201)

[*] Having recognized the possibility of rejecting a Markush group type of claim on the basis of independent and distinct inventions, the PTO may wish to anticipate and forestall procedural problems by exercising its rulemaking powers under 35 USC 6(a), wherein the views of interested parties may be heard.